DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 31, 2017

Advanced Sterilization Products
Ms. Laurie Cartwright
Associate Director, Regulatory Affairs
33 Technology Drive
Irvine, CA 92618

Re: K163598
Trade/Device Name: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator
Regulation Number: 21 CFR 880.6850 /21 CFR 880.2800
Regulation Name: Sterilization Wrap/Sterilization Process Indicator
Regulatory Class: Class II
Product Code: KCT, JOJ
Dated: July 05, 2017
Received: July 07, 2017

Dear Laurie Cartwright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark S. Fellman -S

for

Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K163598

Device Name
Tyvek® Pouch/Roll with STERRAD® Chemical Indicator

Indications for Use *(Describe)*

Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD Sterilization Systems and Cycles, in a single or double pouch configuration, and to indicate, by color change, that the pouch has been exposed to sterilant. After completion of the sterilization process, the pouch/roll is intended to maintain sterility of the enclosed device until used.

The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2014 [Type I]) that changes from red to the color indicated on the comparator bar included on the shelf pack (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD Sterilization Systems.

The pouches and rolls can be used in the STERRAD Sterilization Systems and Cycles shown in Table 1.

Table 1- Indications for Use

STERRAD® / Cycle		**Single-channel stainless steel lumens**	**Other lumens**	**Load requirements**
STERRAD® 100S		≥1 mm ID x ≤125 mm long ≥2 mm ID x ≤250 mm long ≥3 mm ID x ≤400 mm long	Metal and nonmetal ≥6 mm ID x ≤310 mm long	≤10 lumens per load
STERRAD NX® with or without ALLClear™ Technology	STANDARD	≥1 mm ID x ≤150 mm long ≥2 mm ID x ≤400 mm long	N/A	≤10 lumens per load ≤10.7 lbs
	ADVANCED	≥1 mm ID x ≤500 mm long	N/A	≤10 lumens per load ≤10.7 lbs
STERRAD® 100NX with or without ALLClear™ Technology	STANDARD	≥0.7 mm ID x ≤500 mm long	N/A	≤10 lumens per load ≤21.4 lbs
	EXPRESS	N/A	N/A	≤10.7 lbs on bottom shelf only
	DUO	N/A	N/A	Accessory devices (e.g., cameras and light cords) only 2 cameras maximum

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Advanced Sterilization Products
Tyvek® Pouch/Roll with STERRAD® Chemical Indicator with Extended Post-Processing Shelf-Life

General Information

Submitter Name:	Advanced Sterilization Products Division of Ethicon, Inc., a Johnson & Johnson company
Address:	33 Technology Drive Irvine, CA 92618
Contact Person:	Laurie Cartwright Associate Director, Regulatory Affairs Telephone: (949) 789-3877 Email: lcartwr@its.jnj.com
Date Prepared:	July 26, 2017
510(k) Number:	K163598

Device Name

Proprietary Name:	Tyvek® Pouch/Roll with STERRAD® Chemical Indicator
Common Name:	Sterilization Pouch/Roll with Chemical Indicator
Classification Name:	Sterilization Wrap/Sterilization Process Indicator
Device Class:	Class II
Product Code:	KCT JOJ
CFR Section:	21 CFR 880.6850 21 CFR 880.2800

Predicate Device

Tyvek Pouch/Roll with STERRAD Chemical Indicator cleared under K141693.

Device Description

The modified Tyvek Pouch/Roll with STERRAD Chemical Indicator is constructed from Tyvek plastic films, with the STERRAD Chemical Indicator printed onto the Tyvek film. The self-seal pouch permits sealing of the pouch without need of heat-sealing equipment, while the heat sealed pouches and rolls are heat sealed prior to processing in the STERRAD Sterilization Systems.

The modified Tyvek Pouch/Roll with STERRAD Chemical Indicator is intended to enclose medical devices to be terminally sterilized in the STERRAD Sterilization Systems in a single or double pouch configuration. The medical devices are inserted into the pouch/roll, sealed, and then sterilized in the STERRAD Sterilization System.

The only difference between the modified device and the predicate device, is the increased post-processing shelf-life to 12 months.

The STERRAD Chemical Indicator offers an additional way to verify processing in the sterilization cycle. The Chemical Indicator should be used in addition to, not in place of, the biological indicator. STERRAD

Chemical Indicators do not signify sterilization; they only indicate that the indicator has been exposed to the hydrogen peroxide. The color of the Chemical Indicator changes from red to the color indicated by the comparator bar included on the shelf pack (or lighter) when exposed to hydrogen peroxide.

The product codes for all Tyvek Pouches and Rolls with STERRAD Chemical Indicator are shown in the following table:

Product Type	Product Codes
Tyvek Self-Seal Pouches with STERRAD Chemical Indicator (123XX)	12320, 12326, 12335, 12332, 12342, 12340, 12348, 12356
Tyvek Rolls with STERRAD Chemical Indicator (124XX)	12407, 12410, 12415, 12420, 12425, 12435, 12442, 12450
Tyvek Heat-Seal Pouches with STERRAD Chemical Indicator (125XX)	12521, 12526, 12532, 12541, 12548, 12543*, 12544*, 12557*, 12558*, 12559*, 12560*

* Indicates Product Codes exclusively for markets outside the USA.

Intended Use/Indications for Use

The intended use of the Tyvek Pouch/Roll with STERRAD Chemical Indicator, as described in the 21 CFR 880.6850/21 CFR 880.2800, has not changed as a result of the proposed modification. The Tyvek Pouch/Roll with STERRAD Chemical Indicator (predicate and modified device) is intended to enclose a medical device that is to be sterilized in the STERRAD Sterilization System, and to indicate that the pouch/roll has been exposed to hydrogen peroxide during the sterilization process.

The modified device indication for use is provided below:

Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD Sterilization Systems and Cycles, in a single or double pouch configuration, and to indicate, by color change, that the pouch has been exposed to sterilant. After completion of the sterilization process, the pouch/roll is intended to maintain sterility of the enclosed(s) device until used.

The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2014 [Type I]) that changes from red to the color indicated on the comparator bar included on the shelf pack (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD Sterilization Systems.

The pouches and rolls can be used in the STERRAD Sterilization Systems and Cycles shown in Table 1.

Table 1- Indications for Use

STERRAD® / Cycle		Single-channel stainless steel lumens	Other lumens	Load requirements
STERRAD® 100S		≥1 mm ID x ≤125 mm long ≥2 mm ID x ≤250 mm long ≥3 mm ID x ≤400 mm long	Metal and nonmetal ≥6 mm ID x ≤310 mm long	≤10 lumens per load
STERRAD NX® with or without ALLClear™ Technology	STANDARD	≥1 mm ID x ≤150 mm long ≥2 mm ID x ≤400 mm long	N/A	≤10 lumens per load ≤10.7 lbs
	ADVANCED	≥1 mm ID x ≤500 mm long	N/A	≤10 lumens per load ≤10.7 lbs
STERRAD® 100NX with or without ALLClear™ Technology	STANDARD	≥0.7 mm ID x ≤500 mm long	N/A	≤10 lumens per load ≤21.4 lbs
	EXPRESS	N/A	N/A	≤10.7 lbs on bottom shelf only
	DUO	N/A	N/A	Accessory devices (e.g., cameras and light cords), only 2 cameras maximum

Non-Clinical Data

Verification testing was conducted in support of the extended post-processing shelf-life to the Tyvek Pouch/Roll with STERRAD Chemical Indicator that is the subject of this submission; all testing yielded passing results. This testing is summarized in the following table.

Summary of Performance Testing

Verification Testing	Description	Results (Pass/Fail)
Maintenance of Package Integrity	12 Months Sterility Maintenance of the Tyvek Pouches/Rolls with STERRAD Chemical Indicator Post Processing using the STERRAD 100S Sterilization System	Pass
Maintenance of Package Integrity	12 Months Sterility Maintenance of the Tyvek Pouches/Rolls with STERRAD Chemical Indicator Post Processing in the STERRAD 100S Sterilization System using LONG Cycle	Pass
Maintenance of Package Integrity	12 Months Sterility Maintenance of the Tyvek Pouches/Rolls with STERRAD Chemical Indicator Post Processing in the STERRAD NX Sterilization System using ADVANCED Cycle	Pass
Maintenance of Package Integrity	12 Months Sterility Maintenance of the Tyvek Pouches/Rolls with STERRAD Chemical Indicator Post Processing in the STERRAD NX Sterilization System using STANDARD Cycle	Pass
Maintenance of Package Integrity	12 Months Sterility Maintenance of the Tyvek Pouches/Rolls with STERRAD Chemical Indicator Post Processing in the STERRAD 100NX Sterilization System using STANDARD Cycle	Pass
Maintenance of Package Integrity	12 Months Sterility Maintenance of the Tyvek Pouches/Rolls with STERRAD Chemical Indicator Post Processing in the STERRAD 100NX Sterilization System using EXPRESS Cycle	Pass
Maintenance of Package Integrity	12 Months Sterility Maintenance of the Tyvek Pouches/Rolls with STERRAD Chemical Indicator Post Processing in the STERRAD 100NX Sterilization System using DUO Cycle	Pass

Clinical Data

No clinical data was submitted in support of this Premarket Notification.

Summary

The Tyvek Pouch/Roll with STERRAD Chemical Indicator with Extended Post-Processing Shelf-Life and its predicate device, the Tyvek Pouch/Roll with STERRAD Chemical Indicator cleared under K141693, have the same intended use, technological characteristics, design, materials, and principles of operation. Results of maintenance of package integrity verification studies demonstrated that after completion of the sterilization process, the modified device maintains sterility of enclosed medical device(s) for a period of 12 months compared to period of 30 days for the predicate device. Furthermore, the modified device indication for use statement has been updated for clarity (including moving of the post processing shelf-life dating to the description section of the Instruction for Use). Refer to the following tables for comparisons between the modified and the predicate device characteristics.

Comparison of Device Characteristics

	Predict Tyvek® Pouch/Roll with STERRAD® Chemical Indicator (K141693)	Modified Device: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator with Extended Post-Processing Shelf-Life (K163598)
Intended Use	The Tyvek Pouch/Roll with STERRAD Chemical Indicator is intended to enclose a medical device that is to be sterilized in the STERRAD Sterilization System, and to indicate that the pouch/roll has been exposed to hydrogen peroxide during the sterilization process.	Same
Indications for Use	Tyvek Pouches and Rolls with STERRAD Chemical Indicator are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD Sterilization Systems and Cycles, in a single or double pouch configuration, and to indicate, by color change, that the pouch has been exposed to sterilant. After completion of the sterilization process, the pouch/roll maintains sterility until the pouch/roll is used; in the United States, this is for a period of 30 days. The STERRAD Sterilization Systems and Cycles that can be used are shown in Table 1. The product codes for all Tyvek Pouches and Rolls with STERRAD Chemical Indicator are listed in Table 2. The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to yellow (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD Sterilization Systems.	Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD Sterilization Systems and Cycles, in a single or double pouch configuration, and to indicate, by color change, that the pouch has been exposed to sterilant. After completion of the sterilization process, the pouch/roll is intended to maintain sterility of the enclosed device(s) until used. The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2014 [Type I]) that changes from red to the color indicated on the comparator bar included on the shelf pack (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD Sterilization Systems. The pouches and rolls can be used in the STERRAD Sterilization Systems and Cycles shown in Table 1.

<table>
<tr><th></th><th>Predict Tyvek® Pouch/Roll with STERRAD® Chemical Indicator (K141693)</th><th>Modified Device: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator with Extended Post-Processing Shelf-Life (K163598)</th></tr>
<tr><td></td><td>
Table 1: Indications for Use
<table>
<tr><th colspan="2">STERRAD® / Cycle</th><th>Single-channel stainless steel lumens</th><th>Other lumens</th><th>Load requirements</th></tr>
<tr><td colspan="2">STERRAD® 100S</td><td>≥1 mm ID x ≤125 mm long
≥2 mm ID x ≤250 mm long
≥3 mm ID x ≤400 mm long</td><td>Metal and nonmetal ≥6 mm ID x ≤310 mm long</td><td>≤10 lumens per load</td></tr>
<tr><td colspan="2">STERRAD® 50</td><td>≥1 mm ID x ≤125 mm long
≥2 mm ID x ≤250 mm long
≥3 mm ID x ≤400 mm long</td><td>Metal and nonmetal ≥6 mm ID x ≤310 mm long</td><td>≤10 lumens per load</td></tr>
<tr><td colspan="2">STERRAD® 200</td><td>≥1 mm ID x ≤125 mm long
≥2 mm ID x ≤250 mm long
≥3 mm ID x ≤400 mm long</td><td>Teflon® and polyethylene ≥6 mm ID x ≤310 mm long</td><td>≤12 lumens per load ≤36.48 lbs</td></tr>
<tr><td rowspan="2">STERRAD® NX®</td><td>Standard</td><td>≥1 mm ID x ≤150 mm long
≥2 mm ID x ≤400 mm long</td><td>N/A</td><td>≤10 lumens per load ≤10.7 lbs</td></tr>
<tr><td>Advanced</td><td>≥1 mm ID x ≤500 mm long</td><td>N/A</td><td>≤10 lumens per load ≤10.7 lbs</td></tr>
<tr><td rowspan="3">STERRAD® 100NX®</td><td>Standard</td><td>≥0.7 mm ID x ≤500 mm long</td><td>N/A</td><td>≤10 lumens per load ≤21.4 lbs</td></tr>
<tr><td>EXPRESS</td><td>N/A</td><td>N/A</td><td>≤10.7 lbs on bottom shelf only</td></tr>
<tr><td>DUO</td><td>N/A</td><td>N/A</td><td>Accessory devices (e.g., cameras and light cords) only 2 cameras maximum</td></tr>
</table>
Table 2: Product Codes for Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator
<table>
<tr><th>Product Type</th><th>Product Codes</th></tr>
<tr><td>Tyvek® Self-Seal Pouches with STERRAD® Chemical Indicator (123XX)</td><td>12320, 12326, 12335, 12332, 12342, 12340, 12348, 12356</td></tr>
<tr><td>Tyvek® Rolls with STERRAD® Chemical Indicator (124XX)</td><td>12407, 12410, 12415, 12420, 12425, 12435, 12442, 12450</td></tr>
<tr><td>Tyvek® Heat-Seal Pouches with STERRAD® Chemical Indicator (125XX)</td><td>12521, 12526, 12532, 12541, 12548</td></tr>
</table>
</td><td>
Table 1- Indications for Use
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≥3 mm ID x ≤400 mm long</td><td>Metal and nonmetal ≥6 mm ID x ≤310 mm long</td><td>≤10 lumens per load</td></tr>
<tr><td rowspan="2">STERRAD NX® with or without ALLClear™ Technology</td><td>STANDARD</td><td>≥1 mm ID x ≤150 mm long
≥2 mm ID x ≤400 mm long</td><td>N/A</td><td>≤10 lumens per load ≤10.7 lbs</td></tr>
<tr><td>ADVANCED</td><td>≥1 mm ID x ≤500 mm long</td><td>N/A</td><td>≤10 lumens per load ≤10.7 lbs</td></tr>
<tr><td rowspan="3">STERRAD® 100NX with or without ALLClear™ Technology</td><td>STANDARD</td><td>≥0.7 mm ID x ≤500 mm long</td><td>N/A</td><td>≤10 lumens per load ≤21.4 lbs</td></tr>
<tr><td>EXPRESS</td><td>N/A</td><td>N/A</td><td>≤10.7 lbs on bottom shelf only</td></tr>
<tr><td>DUO</td><td>N/A</td><td>N/A</td><td>Accessory devices (e.g., cameras and light cords) only 2 cameras maximum</td></tr>
</table>
</td></tr>
<tr><td>Materials of Construction</td><td>Tyvek and transparent plastic film</td><td>Same</td></tr>
<tr><td>Pouch Types</td><td>Self-Seal Pouch (123XX), Heat-Seal Pouch (125XX), and Heat-Seal Roll (124XX)</td><td>Same</td></tr>
</table>

	Predict Tyvek® Pouch/Roll with STERRAD® Chemical Indicator (K141693)	**Modified Device: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator with Extended Post-Processing Shelf-Life (K163598)**
Design Features	Two films which are heat sealed together on three sides for individual pouches and on two sides for roll form pouches. A Chemical Indicator (CI) bar is printed onto the Tyvek side of the pouch. For the self-seal pouch, the CI is printed onto back surface of the Tyvek. For the heat-seal pouch and roll, the CI is printed onto the Tyvek, but is encased in the seam of the pouch between the Tyvek and transparent film.	Same
Chemical Indicator	STERRAD indicator ink	Same
Chemical Indicator Device Design	The color of the Chemical Indicator changes from red to color indicated by comparator bar (or lighter) when exposed to hydrogen peroxide vapor during the sterilization process in the STERRAD Sterilization Systems.	Same
Post-Processing Sterility Shelf-Life	30 days	12 months

Comparison of Biocompatibility and Performance Testing

	Predict Tyvek® Pouch/Roll with STERRAD® Chemical Indicator (K141693)	**Modified Device: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator with Extended Post-Processing Shelf-Life**
Biocompatibility	*In vivo* testing demonstrated that the pouch samples, after STERRAD processing, met the acceptance criteria per ISO 10993-11 and 10993-10 and can be safely used.	No new testing. Predicate Device testing applies to modified device; no change to device materials
End Point / Post Processing Color Stability	Tyvek Pouches/Rolls, after STERRAD processing, maintained the endpoint CI color reaction.	No new testing. Predicate Device testing applies to modified device; no change to device materials
Material Compatibility	Seal strength test, microbial barrier properties, burst test, and peel open test demonstrated acceptable material compatibility characteristics of the Tyvek Pouches/Rolls after STERRAD processing	No new testing. Predicate Device testing applies to modified device; no change to device materials
Sterilant Penetration Efficacy	The sterilant penetrated through the "double pouch" configuration under the worst case half-cycle conditions and the sterility assurance level (SAL) of 10^{-6} was demonstrated.	No new testing. Predicate Device testing applies to modified device; no change to device materials
Seal Strength	Seal strength of the processed Tyvek Pouches/Rolls is maintained at the end of pre-processing shelf life.	No new testing. Predicate Device testing applies to modified device; no change to device materials
Chemical Indicator (CI) Functionality	CI functionality of the processed Tyvek Pouches/Rolls is maintained at the end of pre-processing shelf life.	No new testing. Predicate Device testing applies to modified device; no change to device materials
Maintenance of Package Integrity	30 days sterility maintenance post processing in STERRAD Sterilizers	12 months sterility maintenance post processing in STERRAD Sterilizers

In conclusion, the intended use, operating principle, performance specification, material and design of the modified device are same as the predicate device and the minor differences between the modified device and its predicate device do not raise any new questions of safety or effectiveness. Thus, the Tyvek Pouch/Roll with STERRAD Chemical Indicator with Extended Post-Processing Shelf-Life is substantially equivalent to the predicate device cleared in K141693.